AUG 2 3 2001

K011698

ATTACHMENT 8 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert, Director of Regulatory Affairs

2. **Name of the Device**

Trade Name:	Straumann GBR System
Common Name:	Craniomaxillofacial Fixation Plates, Meshes and Screws, membrane fixation screws
Classification Name:	Bone plate, 21 CFR § 872.4760, Class II Intraosseous fixation screws, 21 CFR § 872.4880, Class II Surgical Mesh, 21 CFR § 878.3300, Class II

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

MODUS® System Plates, Mesh, and Screws (K946165)
Implant Innovations OsseoFix System (K960914)
Straumann Memfix screws (K955369)
Leibinger Bone Grafting System
Leibinger M-TAM
TiMesh titanium mesh cribs

4. **Description of the Device**

The Straumann GBR System is comprised of bone plates, meshes, screws, and accompanying instruments. The cranial plates are offered in 2, 4, and 6 hole options. Screws with diameters of 1.2 and 1.5mm are used to secure the cranial plates in place. The plates and screws are composed of commercially pure Grade 4 titanium meeting ASTM F67.

The 0.9 and 1.5 mesh are available in uniform mesh size and pattern, and alternating mesh size and patterns. Screws with diameters of 1.2 and 1.5mm are used to secure the mesh in place. The meshes are composed of commercially pure Grade 1 titanium meeting ASTM F67.

The Straumann GBR System also includes a fixation screw used to stabilize and adapt the membranes. There are two variations of supporting screws which prevent the membrane from collapsing into the defect site, and in conjunction

with a head screw, provide membrane fixation and support. The screws are composed of stainless steel.

5. **Intended Use of the Device**

The Straumann GBR System is intended for use in stabilizing and fixating bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. The GBR technique can make it possible for the placement of dental implants in previously unsuitable sites.

6. **Basis for Substantial Equivalence**

The Straumann GBR System is substantially equivalent in intended use to the previously cleared MODUS® Titanium Osteosynthesis System, Implant Innovations OsseoFix System, Straumann Memfix screws, Leibinger's Bone Grafting and M-TAM Systems, and TiMesh titanium mesh cribs. The plates, screws, and meshes are similar, and in some cases identical, to previously cleared MODUS® craniofacial plates and meshes and screws. The plates and screws are composed of CP Grade 4 titanium, which is the identical material to previously cleared MODUS® plates and screws. The meshes are composed of CP Grade 1 titanium, the identical material as that of previously cleared MODUS® mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Institut Straumann AG
C/O Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K011698
Trade/Device Name: Straumann GBR System
Regulation Number: 872.4760 and 872.4880
Regulatory Class: II
Product Code: JEY and DZL
Dated: May 31, 2001
Received: June 1, 2001

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011698

Device Name: Straumann Guided Bone Regeneration System

Indications For Use:

The Straumann Guided Bone Regeneration (GBR) System is used to stabilize and fixate bone grafts, bone filling materials, and/or barrier membranes used for regeneration of bone in the oral cavity. The GBR technique can make it possible for the placement of dental implants in previously unsuitable sites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Gerald W Stupp for MSR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011698